REMARKS

A. REQUEST FOR RECONSIDERATION

Applicant has carefully considered the matters raised by the Examiner in the outstanding Office Action dated March 13, 2007, but remains of the opinion that patentable subject matter is present. Applicant respectfully requests reconsideration of the Examiner's position based on the amendments to the claims and the following remarks.

B. STATUS OF THE CLAIMS

Claims 1, 3-21, 23-38, 40-64, 69-74, 78-83, 87-89, 93, and 99-146 are pending in this application. Claims 75 and 76 are cancelled without prejudice. Claims 1, 11, 23, 28, 40, 78, 117 and 122 are amended and Claims 123-146 have been added herein to describe a further aspect which Applicants consider to be their invention. No new matter has been added.

C. AMENDMENTS

Claim 1 has been amended to recite that the formoterol, or a pharmaceutically acceptable salt or hydrate thereof is in solution. Support for this amendment can be found, for example, on Page 36, lines 7-9. Claim 1 has also been amended to recite that the steroidal anti-inflammatory agent, or a pharmaceutically acceptable salt or hydrate thereof is in suspension. Support for this amendment can be found, for example, on Page 36, line 9. Claim 1 has also been amended to recite that the upper limit for the formoterol is about 200 μg/mL. Support for this amendment can be found, for example in original Claim 24, and Page 16, lines 25-29. Claim 1 has also been amended to recite that 90% of the initial amount of formoterol remains in the composition after storing for greater than 1 month at 25 °C and greater than or equal to 1 year at 5 °C. Support for this amendment can be found, for example on Page 4, lines 3-7. Finally, Claim 1 has been amended to more clearly recite that the pharmacologically suitable fluid comprises water.

Claims 11 and 28 have been amended to correct a typographical error.

Similar to Claim 1, Claims 23 and 40 have been amended to recite that the upper limit for the formoterol is about 200 μg/mL.

Support for the amendments made to Claims 78, 117 and 122 can also be found, for example, in the same places where it was shown for Claim 1.

Support for new Claims 123-126 can be found, for example, on Page 6, line 20 to Page 7, line 28.

Support for new Claims 127-128 can be found, for example, on Page 20, line 29 to Page 21, line 28, Page 24, line 12 to Page 25, line 10, and Page 19, line 5 to Page 20, line 17.

Support for new Claims 129-136 and 140-143 can be found, for example, on Page 1, line 11, Page 6, line 17-Page 7, line 6, Page 16, lines 20-29, Page 20, lines 6-7, Page 18, lines 16-20, and Page 33, line 28-Page 34, line 4.

Support for new Claims 137-139 and 144-146 can be found, for example, on Page 6, lines27-28.

D. ARGUMENTS

Along with the amendments made to the claims herein, Applicants wish to provide further arguments which traverse the rejections made in the final Office Action dated March 13, 2007. At the outset, the undersigned hereby incorporates by reference, all remarks made in the last response to the prior art rejections made of record by the Examiner.

I. THE AMENDED CLAIMS ARE NOT OBVIOUS OVER HOCHRAINER IN VIEW OF ANY COMBINATION OF REFERENCES RELIED UPON BY THE EXAMINER.

In an effort to advance the prosecution of the present application, Applicants have amended the claims to recite that the upper limit of the formoterol concentration is 200 μg/mL. It is noted that in addition to all of the comments previously made concerning Hochrainer (U.S. 6,150,418), there is no disclosure or suggestion therein to prepare such compositions having at most 200 μg/mL. In fact, the lowest formoterol concentration disclosed therein is 900 μg/mL, almost 5 times more concentrated than the claimed concentration in the present application.

Furthermore, Hochrainer does not teach any particular steroid, nor is there any disclosure regarding the concentration of the steroid in the formulation. Thus, neither Hochrainer nor any other reference relied upon by the Examiner teaches to provide formoterol and a steroidal anti-inflammatory agent in such amounts in aqueous solution or suspension suitable for long-term storage and direct administration as is claimed in the present application.

Hochrainer explicitly teaches a pharmaceutical preparation that is not stable for long-term storage. Hochrainer teaches a composition in which formoterol is highly concentrated in order to be capable of long-term storage without deterioration in pharmaceutical quality (Column 1, lines 56-61). This highly concentrated composition is not suitable as a pharmaceutical preparation (Column 2, lines 1-4). Rather, Hochrainer discloses that a composition suitable for administration is preferably diluted so that the formoterol concentration is 900 μg/mL (Column 4, lines 26-28). The independent claims in the present application require no greater than 200 μg/mL of formoterol. This is almost a 5-fold decrease in formoterol concentration as compared to the composition of Hochrainer that was not suitable for long-term storage.

Furthermore, Hochrainer does not teach a pharmaceutical preparation having formoterol in solution and a steroidal anti-inflammatory agent in suspension. Applicants have amended the claims to recite that formoterol is in solution and a steroidal anti-inflammatory agent is in suspension. There is no disclosure in Hochrainer, or in any of the other references cited by the Examiner, to prepare such compositions. Generally, a formulation having one drug in solution and one drug in suspension is metastable (i.e., not stable). Thus, in order to obtain a stable formulation, either both drugs are in suspension or in solution. Therefore it is unexpected that formulations of the present invention are stable for long-term storage and direct administration as is claimed in the present application.

Thus, the claims are not obvious over Hochrainer and in view of any combination of references relied upon by the Examiner, and the rejection should be withdrawn.

II. NOTHING IN HOCHRAINER OR THE COMBINATIONS OF REFERENCES SUGGESTS THAT SUCH A DILUTE SOLUTION WOULD BE STABLE.

Turning to the second and third obviousness rejections, Applicants reiterate that Hochrainer does not teach that a formulation having formoterol in solution and a steroidal anti-inflammatory agent in suspension would be stable. The Examiner has also cited Blondino et al. (U.S. 6,004,537), Carling et al. (U.S. 5,674,860) and PDR. Applicants have carefully considered the secondary references cited by the Examiner, however, remain of the opinion that none of these references cure the deficiencies of Hochrainer.

In the final obviousness rejection, citing Hardman et al. (Goodman Gilman's *The Pharmacological Basis of Therapeutics*, 1996, page 665) or Leckie et al. (*Novel Therapy* of CPOD, abstract, January 2000), the subject matter of Claims 113-116 and 120-121 was also rejected. Since these claims depend from independent Claim 1, and therefore include all the limitations of the independent claim, it is respectfully urged that these claims patentably distinguish over this combination based principally upon Hochrainer. As pointed out above, the principle reference relied upon by the Examiner does not teach all the limitations of the independent claims. The secondary references do not cure the deficiencies of Hochrainer concerning dilute formoterol-containing compositions. Therefore, the rejection should be withdrawn.

Furthermore, new claims 123-128 depend from claim 1, and therefore include all the limitations of claim 1. Thus, for the reasons set forth above, these claims should also be patentable over the prior art.

New claims 129-146 are also patentable over the prior art. New claims 129-146 are directed to a unit dose of formoterol at a concentration of from about 5 μg/mL to about 200 μg/mL where the composition has an estimated shelf life of greater than 90% after 3 months storage at 25 °C and after 3 years storage at 5 °C. As discussed above, none of the references

teach such dilute formoterol containing compositions that are suitable for long term storage, nor do they teach such formulations that demonstrate the stability as is claimed.

In view of the foregoing, it is respectfully submitted that the claims presented herein are patentable over Hochrainer and in view of any combination of references, and that this application is in condition for allowance and such action is respectfully requested. In the event of non-allowance, it is requested that the Examiner contact Applicants' attorney so that appropriate arrangements can be made to discuss further arguments in support of allowance.

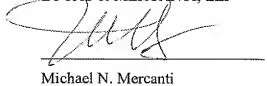
E. CORRECTION OF INVENTORSHIP

This response is being submitted with a request to correct inventorship and fee in accordance with 37 CFR 1.17(i).

F. FEES

The $130.00 processing fee set forth in 37 CFR 1.17(i) is being charged to the undersigned's credit card. No further fee is believed to be due. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

Respectfully submitted,
LUCAS & MERCANTI, LLP



Michael N. Mercanti
Registration No. 33,966

LUCAS & MERCANTI, LLP
475 Park Avenue South
New York, New York 10016
Phone: 212-661-8000
Fax: 212-661-8002